Adding retinal photography to screening for diabetic retinopathy: a prospective study in primary care

J P O'Hare, A Hopper, C Madhaven, M Charny, T S Purewal, B Harney, J Griffiths

Abstract

***Objective*—To evaluate whether adding retinal photography improved community screening for diabetic retinopathy.**

***Setting*—Mobile screening unit at rural and urban general practices in south west England.**

***Subjects*—1010 diabetic patients from primary care.**

***Design*—Prospective study; patients were examined by ophthalmoscopy by general practitioners or opticians without fundal photographs and again with photographs, and assessments were compared to those of an ophthalmologist.**

***Main outcome measures*—Whether fundal photography improved the sensitivity of detection of retinopathy and referrable diabetic retinopathy, and whether this sensitivity could be improved by including a review of the films by the specialist.**

***Results*—Diabetic retinopathy was detected by the ophthalmologist in 205 patients (20·5%) and referrable retinopathy in 49 (4·9%). The sensitivity of the general practitioners and opticians for referrable retinopathy with opthalmoscopy was 65% and improved to 84% with retinal photographs. General practitioners' sensitivity in detecting background retinopathy improved with photographs from 22% to 65%; opticians' sensitivity in detecting background retinopathy improved from 43% to 71%. The sensitivity of detecting referrable retinopathy by general practitioners improved from 56% to 80% with photographs; for opticians it improved from 75% to 88%.**

***Conclusion*—Combining modalities of screening by providing photography with specialist review of all films in addition to direct ophthalmoscopy through dilated pupils improves assessment and referral for diabetic retinopathy by general practitioners and opticians. With further training and experience, primary care screeners should be able to achieve a sensitivity that will achieve an effective, acceptable, and economical community based screening programme for this condition.**

Department of Medicine, Royal United Hospital, Combe Park, Bath BA1 3NG
J P O'Hare, *consultant physician*
A Hopper, *senior medical photographer*
T S Purewal, *senior registrar*

Department of Ophthalmology, Royal United Hospital
C Madhaven, *staff grade ophthalmologist*
B Harney, *consultant ophthalmologist*
J Griffiths, *consultant ophthalmologist*

Wiltshire and Bath Health Commission, Devizes, Wiltshire SN10 5EQ
M Charny, *director of public health*

Correspondence to:
Dr O'Hare.

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Introduction

Diabetes mellitus is the most common cause of blindness in people of working age in the United Kingdom.[1] Diabetic retinopathy accounts for 90% of diabetes related blindness. About 2% of all diabetic patients are currently registered as blind or partially sighted, but many more have not been registered but are greatly handicapped by reduced vision.[2] With effective laser treatment, diabetic retinopathy detected and referred early can be treated and most diabetic patients who would otherwise lose vision or become blind can have their vision saved.[3,4] Even so, the number of registered legally blind diabetic patients in Avon has remained the same for 20 years.[5] Ineffective screening with existing systems may be the major factor in this disappointing performance.[6]

Experts agree that organised retinal screening programmes of sufficient sensitivity would be highly desirable for diabetic patients and should be extremely cost effective.[7] An effectively managed community based screening programme encompassing detection, referral, treatment, and follow up would prevent about 260 new cases of blindness in diabetic patients under the age of 70 each year in England and Wales.[7]

The method for effective screening remains a subject of debate.[8-13] The largest study comparing existing methods, including a health economic analysis, studied 3318 patients in three centres in the United Kingdom. It found an overall sensitivity of 53% (range 41-67%) of ophthalmoscopic screening for sight threatening retinopathy by general practitioners and 48% (26-69%) by ophthalmic opticians. Fundal photography alone achieved a sensitivity of 55% (35-67%). Combined screening with the ophthalmoscope and fundal photographs interpreted by the ophthalmologist improved the detection of sight threatening retinopathy in all groups in all centres to 75% for general practitioners and 67% for opticians.[9] An approach combining modalities, based on this retrospective and other smaller prospective studies, was recently recommended.[14,15]

Mobile retinal screening units with a fundal camera mounted in a converted vehicle allow the facility of the retinal camera to be available to rural general practices. Large studies have shown that these improve on existing methods of screening used in the hospital and community setting.[16,17] We studied 1010 patients with diabetes cared for in primary care, evaluating whether the combination of retinal photography and ophthalmoscopy through dilated pupils when carried out by interested general practitioners or opticians is superior to either modality alone. The study had four end points: whether fundal photos improved sensitivity of detection of both retinopathy and referrable diabetic retinopathy; whether this sensitivity could be improved further by including a review of the films by the specialist; whether, when compared to a reference standard, the performance of general practitioners differed from that of opticians; and whether specialist photographic assessment alone was different from the result of the combined approach.

Method

General practitioners and ophthalmic opticians already using ophthalmoscopy as part of their clinical annual review of diabetic patients were invited to take part in the study. Instruction was arranged for each general practitioner and optician in the study to explain the method of classifying diabetic retinopathy and the criteria for referrable retinopathy (box). Each was provided with a reference manual of photographs as

Criteria for referral of diabetic patients screened for retinopathy

Referrable criteria are grades 2B-5; general practitioners, opticians, and ophthalmologists used this form to record findings on examination.

	Right eye	Left eye
Manifestations of retinopathy		
1 Mild or moderate background retinopathy	Y N	Y N
2A Maculopathy—microaneurysms or haemorrhage	Y N	Y N
2B Maculopathy—exudates within 2 discs of fovea (especially circinate or part circinate)	Y N	Y N
2C Maculopathy—retinopathy and (corrected) loss of visual acuity < 6/9	Y N	Y N
3 Pre-proliferative retinopathy (more than 2 cotton wool spots, venous beading, or loops; severe background retinopathy (widespread blotchy haemorrhages, etc)	Y N	Y N
4 Vitreous or pre-retinal haemorrhage (subhyaloid)—present or previous history	Y N	Y N
5 Proliferative retinopathy (new vessels anywhere; fibrous tissue formation)	Y N	Y N
6 Non-diabetic retinopathy (eg colloid bodies, chorioretinitis, macular degeneration)	Y N	Y N
Action		
7A Referred to ophthalmologist for diabetic retinopathy (2B, 2C, 3, 4, 5)		Y N
7B Referred to ophthalmologist for non-diabetic retinopathy (6) (Specify.....)		Y N
7C Referred to ophthalmologist for other condition (Specify.....)		

examples of diabetic retinopathy to illustrate typical fundal appearances, with the grading and referral action clearly explained. These classifications and referral criteria followed the advice of the ophthalmologists involved in the study. The reference standard of the study was the ophthalmologists' categorisation after fundal examination and review of photographs taken at screening. The fundal photographs were later assessed in a single blinded manner by the ophthalmologist.

Patients who had been seen in hospital diabetic or ophthalmological clinics in the past 12 months were excluded, as were those already blind and those unable to mount the steps of the retinal screening van.

STUDY PROTOCOL

The mobile retinal screening unit (funded by the British Diabetic Association) with driver-photographer and staff grade ophthalmologist travelled out to participating practices. Patients had their corrected visual acuity recorded and then had the fundi dilated with 0·5% tropicamide (two drops to each eye). A single photograph centred on the macula was taken with a retinal camera with instantaneous picture development (Canon CR445NM). Patients were then examined by the general practitioner or optician by ophthalmoscopy; findings and need for referral were recorded on Form A (box). The general practitioners or opticians were then given the fundal photographs to evaluate; with this information they reassessed the previous grading and referral decision and completed a second form (form B). The identical procedure was then carried out by the ophthalmologist (forms C and D).

STATISTICAL ANALYSIS

The study design allowed the assessment of sensitivity, specificity, positive predictive value, and negative predictive value for general practitioners and opticians with and without photographs. A sample size of 1000 assumed a referrable retinopathy rate of 5% to achieve sufficient numbers. Confidence intervals based on the sensitivities of each practice screened were calculated.

Results

A total of 1010 patients (517 examined by general practitioners and 493 by opticians) were studied. Eleven practices were screened by 31 general practitioners and patients from 12 practices were screened by 17 opticians.

Table 1 shows the sensitivity of screening for retinopathy for the general practitioners and opticians. Providing photographs to general practitioners and opticians clearly improved both the correct classification and the appropriate referral of patients with sight threatening diabetic retinopathy (from 65% to 73% for all patients). Specificity (table 2) for referrable retinopathy was high at 97% for general practitioners and 93% for opticians. The difference in specificity meant that opticians referred 52 patients, 21 appropriately, whereas general practitioners referred 31 patients, 15 appropriately.

To improve the sensitivity of detection of sight threatening retinopathy, the photographs were also reviewed by a specialist. For referrable, potentially sight threatening retinopathy this review further improved sensitivity from 73% to 84% (table 1). Later review of the photographs alone achieved 71% sensitivity.

The combination of ophthalmoscopy and photograph review by the general practitioner or optician with subsequent assessment of photographs by a specialist correctly classified 43 of the 49 referrable patients identified by the ophthalmologist's categorisation. Of the six patients missed, one with maculopathy went on to receive laser treatment within one year and one patient with pre-proliferative retinopathy, two with early maculopathy, and one with moderate background retinopathy continued hospital ophthalmic

Table 1—*Sensitivity (%) of general practitioners and opticians screening diabetic patients for retinopathy*

	Non-referrable retinopathy (1+2A)	Referrable	
		Retinopathy (2B-5)	Total*
General practitioners and opticians			
Fundal examination	33	65	63
Fundal examination plus photo	47	73	70
Addition of specialist review of photos	66	84	79
Photo assessment by specialist only	58	71	54
General practitioners only			
Fundal examination	22	56	55
Fundal examination plus photo	37	60	63
Addition of specialist review of photos	60	80	71
Photo assessment by specialist only	55	68	50
Opticians only			
Fundal examination	43	75	73
Fundal examination plus photo	55	88	79
Addition of specialist review of photos	71	88	88
Photo assessment by specialist only	61	75	58

For gradings see form in box.
*Includes other ocular conditions, particularly cataracts (7C on form).

Table 2—*Specificity and positive and negative predictive values of general practitioners and opticians screening diabetic patients for retinopathy*

	Specificity (%)			Positive predictive value (%)			Negative predictive value (%)		
	GP only	Optician only	Both	GP only	Optician only	Both	GP only	Optician only	Both
Fundal examination									
Non-referrable retinopathy (1+2A)	94	94	94	46	68	59	84	85	86
Referrable retinopathy (2B-5)	98	93	96	61	35	43	98	99	98
All referrable conditions*	97	92	95	60	39	47	96	98	97
Fundal examination plus photo									
Non-referrable retinopathy (1+2A)	92	94	93	51	71	62	86	88	89
Referrable retinopathy (2B-5)	98	99	99	48	40	43	98	99	99
All referrable conditions*	97	98	98	53	42	47	97	98	98
Photo assessed by specialist									
Non-referrable retinopathy (1+2A)	91	92	91	58	73	63	91	92	91
Referrable retinopathy (2B-5)	98	99	99	53	40	46	98	99	99
All referrable conditions*	97	98	98	58	45	50	97	98	98
Photo assessment only									
Non-referrable retinopathy (1+2A)	90	90	90	80	83	82	90	90	90
Referrable retinopathy (2B-5)	97	99	99	94	82	88	97	99	99
All referrable conditions*	95	96	97	87	79	81	95	96	97

*Includes other ocular conditions, particularly cataracts (7C on form).
For gradings see form in box.

Table 3—*Mean (95% confidence interval) sensitivity (%) of screening for retinopathy in diabetic patients. Data for practices have been aggregated*

	General practitioners and opticians	General practitioners only	Opticians only
Non-referrable retinopathy (1+2A)			
Ophthalmoloscopy	33 (21 to 44)	22 (12 to 31)	43 (24 to 62)
Ophthalmoloscopy plus photo	48 (36 to 60)*	39 (21 to 57)	56 (41 to 70)*
Ophthalmoloscopy plus photo plus review	65 (53 to 77)*	60 (41 to 79)*	69 (53 to 54)*
Referrable retinopathy (2B-5)			
Ophthalmoloscopy	70 (53 to 87)	53 (26 to 81)	83 (66 to 109)
Ophthalmoloscopy plus photo	79 (64 to 94)*	64 (35 to 94)	83 (66 to 109)
Ophthalmoloscopy plus photo plus review	86 (74 to 97)*	76 (53 to 99)*	93 (85 to 102)
All referrable conditions†			
Ophthalmoloscopy	74 (59 to 89)	65 (38 to 91)	82 (67 to 97)
Ophthalmoloscopy plus photo	80 (67 to 93)	71 (48 to 95)	87 (75 to 99)
Ophthalmoloscopy plus photo plus review	80 (68 to 92)*	79 (64 to 95)	90 (78 to 102)

For gradings see form in box.
*$P < 0.05$ for ophthalmoscope alone versus combined modalities.
†Includes other ocular conditions, particularly cataracts (7C on form).

review; one patient was returned to primary screening.

For all appropriate referrals (diabetic retinopathy and cataracts) the sensitivity of the primary care screeners was improved by the addition of photographs (from 63% to 70%). When, in addition, the photographs were reviewed by the specialist this increased to 79%, but it was only 54% when photographs alone were seen.

When general practitioners' and opticians' performances were separated, the general practitioners performed with a lower sensitivity (56%) for detecting sight threatening retinopathy than did the opticians (75%), but the wide confidence intervals for each group indicate a considerable heterogeneity of performance between practices (table 3). There was no significant difference between the sensitivity of general practitioners (practice mean 53%; 95% confidence interval 26% to 81%) and of opticians (83%; 66% to 109%).

Discussion

Many studies have compared different modalities of screening for diabetic retinopathy[2,8-17]; this study assessed the combination of a single retinal photograph taken through dilated pupils and ophthalmoscopy. It was carried out by interested general practitioners or ophthalmic opticians in the primary care setting. The results show that adding retinal photographs improves the sensitivity of screening without affecting specificity in detecting all grades of retinopathy and particularly in detecting sight threatening retinopathy. Review of the films by an ophthalmological specialist further improves the sensitivity of screening.

Our study clearly shows that the performance of general practitioners and opticians in detecting the earliest stages of retinopathy requires considerable improvement and that the addition of retinal photography almost doubles the sensitivity achieved by both groups. Screening has traditionally focused on detecting sight threatening retinopathy, but recent studies show that improved metabolic control slows progression of retinopathy; this means that effective screening must now also detect early background changes.[18] General practitioners will need further training in the use of the ophthalmoscope, particularly in better focusing and visualising a wider area of the retina, to improve standards.

Although no power calculation was made before the study, we assumed that among 1000 patients, 50 would have sight threatening retinopathy and that this number would give enough confidence for the interpretation of results. While this is true for the addition of photography, the numbers when comparing the performance of general practitioners and opticians are too small for any difference to be viewed with much confidence. The wide confidence intervals in the performance between practices and the possibility of a selection bias imply that it would be unwise to assume a true difference between the performance of general practitioners and of opticians. The best screeners in each group achieved similar sensitivities; furthermore, the addition of the specialist's review of the photographs tended to equalise their performance.

The sensitivity for any screening should ideally match the reference standard, but in the Exeter limb of the three centre study[9] the hospital physicians detected sight threatening retinopathy with a sensitivity of only 67%. It has been claimed that an adequately supervised hospital diabetic clinic might be able to act as a sensitive method of screening, but there have been few studies or audits to evaluate performance in standard

Key messages

- Diabetes is the most common cause of blindness in adults in Britain; with early diagnosis of changes in the retina, effective treatment can reduce the number of patients who lose their vision
- Ophthalmoscopy alone in primary care misses early diabetic retinopathy and is insensitive as a screening modality
- Using photography in addition to ophthalmoscopy, general practitioners and opticians can increase the correct and early diagnosis of sight threatening and background retinopathy
- The sensitivity of screening is further improved by having a specialist assess the photographs
- This method is highly cost effective: it costs £12.50 per patient screened to provide photographs—an estimated £1100 per patient whose sight is saved

hospital diabetic clinics and those that have been carried out have been in centres with a particular interest. In the large Newcastle study of retinal photography, fundal photographs added to ophthalmoscopy considerably improved hospital doctors' screening in diabetic clinics,[16] implying that in many hospital diabetic clinics the screening sensitivity is not dissimilar to the 67% obtained in Exeter.

WHO SHOULD SCREEN?

A further objective of the study was to see if there was a difference between the performance of general practitioners and opticians as primary care screeners for diabetic retinopathy. General practitioners and opticians studied equal numbers of patients, and the number of positive results on screening shows that results in the groups were similar and that the patient populations studied were comparable. Different total numbers of general practitioners and opticians (31:17) in the area agreed to take part in the study—the study had to rely on using those who volunteered, and it is possible that a selection bias exists because of this.

For the population of an average health district (250 000) the service will identify 100-125 diabetic patients whose sight is threatened and who need ophthalmological review, and 50 will need laser treatment. If 80% of sight threatened patients are saved by treatment from losing vision this service will be highly cost effective—each patient saved from visual loss will cost £1095. Our cost for adding photographs (including capital replacement costs) was £12.50 per patient screened. For a district with a diabetic population of 3500 the total cost for adding retinal photographs would be £43 750; the cost for screening these patients in a hospital eye or diabetes clinic would be about £266 000, based on a charge for new patients in an outpatient clinic in 1996 of £76. On the basis of this study, Wiltshire Health Commission has funded the operational costs of the screening service for diabetic patients in primary care since 1993 in the area served by the Royal United Hospital, Bath (£35 000 a year for 3500 patients screened).

We believe that an organised, primary care based, screening programme for diabetic retinopathy that combines ophthalmoscopy and retinal photography could reduce new cases of blindness caused by diabetes. Such programmes could meet the target set by the St Vincent's Declaration[19] of reducing this preventable tragedy by one third or more by the year 2000.

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A MEMORABLE PATIENT

Tingling fingers

My patient was complaining of paraesthesia in her fingers and she also had a patch on her arm; suspiciously scaley and erythematous. When you work in a leprosy endemic country you have to consider leprosy in the differential diagnosis of any skin or nerve lesion, even when the patient is an ex-patriate.

She gave a history of variation from day to day in the tingling—definitely worse on Wednesdays and Fridays. That would have been unusual in leprous neuritis, but it immediately gave a clue to the correct identification of an occupational cause. This young lady spent many hours every week in a research laboratory setting up her enzyme linked immunosorbent assay (ELISA) plates, which requires small quantities of reagent to be accurately added by manual pipette to numerous small wells. This is a task which stresses the hand as well as the powers of concentration.

The diagnosis was agreed to be pipettitive strain injury and clearly the necessary treatment was to take leave and go out trekking—a pleasant occupation which stresses the legs while resting the hands. But enthusiastic PhD students do not readily accept such advice. The experiments had to be finished before the field trip came to an end with the expiry of her visa. No one else can do your experiments for you if you aspire to being a doctor of philosophy. So she had to be content with merely a diagnosis and the expectation of recovery on her return to her home country when she could exchange the laboratory for a library while planning the next set of experiments.

The arm patch was not leprosy; it responded well to Whitfield's ointment.—C R BUTLIN *is a medical superintendent in Anandaban, Kathmandu*